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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :
A61N 1/05, 1/36, A61B 5/22

A1

(11) International Publication Number: WO 93/24176

(43) International Publication Date: 9 December 1993 (09.12.93)

(21) International Application Number: PCT/GB93/01059

(22) International Filing Date: 21 May 1993 (21.05.93)

(30) Priority data:
9211085.7 23 May 1992 (23.05.92) GB

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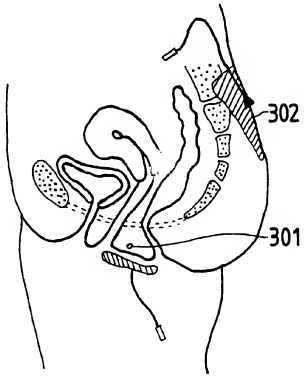
(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ELECTRICAL STIMULATION FOR TREATMENT OF INCONTINENCE AND OTHER NEURO-MUSCULAR DISORDERS

(57) Abstract

The invention is concerned with electrical stimulation for the treatment of neuro-muscular disorders, in particular incontinence. There is disclosed a portable electrical stimulation apparatus for treatment of incontinence, comprising one or more electrodes (302) for applying one or more electrical stimulation signals to a patient's body, a signal generator for generating the electrical stimulation signal(s), one or more conductive leads for connecting the signal generator to the electrode(s), to deliver the electrical stimulation signal to the electrode(s); and a power supply, characterised in that the apparatus includes an instruction storage means or a programming means for imparting a set of instructions to the signal generating means, the signal generating means being responsive to the instruction storage means or programming means so that the generated signal adopts signal waveform characteristics selected in accordance with said set of instructions.



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ELECTRICAL STIMULATION FOR TREATMENT OF INCONTINENCE AND OTHER NEURO-MUSCULAR DISORDERS

Technical Field

The present invention relates to electrical nerve and muscle stimulation and particularly although not exclusively to electro-medical treatment for urinary and faecal incontinence, primarily in women but equally adaptable for men.

Background Art

Conventional electro-stimulation treatments for urinary and faecal incontinence require a patient to apply stimulation via an internal electrode in electrical contact with the body. Treatment is applied for periods ranging from 10 minutes to several hours each day.

A conventional electro-stimulation system includes pulse generator housed in a portable battery box, and an electrode pad for attachment to the patient. Such systems are often used for the relief of chronic back pain or induced muscle contraction. These systems fall under the general classification of transcutaneous electrical nerve stimulation systems (TENS).

The above mentioned electro-stimulation systems conventionally use a drive signal to the electrode which is characterised by a sine wave, square wave, or spike impulse geometry, and is either monophasic capacitively coupled monophasic, biphasic or asymmetric. Differing therapeutic effects are achieved using different drive signal types. Conventionally such stimulation systems allow for a variation of drive signal pulse width or frequency by the patient. However each such known portable stimulation

system has electronics which are dedicated for providing a specific predetermined drive signal having a geometry and other characteristics matched to the intended therapeutic effect. Adjustment of the control signal is conventionally provided by electronic push switches and or rotational control knobs. Such switches and knobs can often be tampered with by the patient, and it is thus difficult for a medical practitioner prescribing electro-stimulation treatment to control the treatment when the patient is away from a clinic.

Other known electro-stimulators include microprocessor based units, but these have a problem that conventionally, specialised pre-programming equipment needs to be used at the clinic to set the signal parameters. Such equipment is expensive and often difficult to use.

Specific embodiments of the present invention aim to provide electro-stimulation apparatus which can be adjusted and preset by a medical practitioner, medical assistant or clinician without requiring of them electronic or computer literacy, and once set is tamper proof by a patient.

In the treatment of incontinence, it is known to use a vaginal or rectal electrode comprising a moulded plastic plug which is insertable into the body. Such plugs may be rigid, semi-rigid or of the expanding coil type. However, these known internal electrodes are uncomfortable and problematic due to their fixed size, difficulty to insert and poor contact with the body, producing

uncomfortable sudden increases in pulse strength. Subsequently, patients dislike such treatments and compliance with the treatment is poor.

Surface electrodes of metal, metallised foil, carbonized rubber and other similar thin conductive plate materials are known. However, such materials are insufficiently flexible and can be problematic causing discomfort, soreness and subsequently poor compliance to treatment. The known surface electrodes are unsuitably shaped and sized, and insufficiently flexible for application over the perineal region adjacent to the vaginal and rectal tracts.

Prior art cloth electrodes are known from US 5.038,796 and US 4,708,149. These electrodes are designed for functional electrical stimulation (FES) and the symptomatic treatment of such afflictions as arthritic pain and back pain.

Pelvic Floor Exercises are a known treatment for exercising muscles which control the urinary function. Such exercises require levator ani muscles to be contracted and relaxed regularly during the course of a day or over a period of many weeks, often months.

A known aid for such exercises comprises a pre-formed core of rigid plastics material. Such aids are provided in a set of graded weights, requiring the (female) patient to insert them into a vaginal tract, and retain them in position. However, this is difficult for many patients, because commonly the

smallest available weight available is too heavy, or the size is incorrect. Insertion and renewal of the cores can be problematic.

Another type of known device comprises a foam cushion, which is used to apply pressure at the bladder neck, keeping the bladder neck closed during normal movement and exercise. However, such devices are not intended for, and are unsuitable for performing Pelvic Floor Exercises. The devices must be softened with water prior to use.

Disclosure of the Invention

Specific embodiments of the present invention aim to address the problems associated with conventional plug type electrodes, and the problems encountered in the treatment of incontinence.

Specific embodiments of the present invention aim to provide an improved Pelvic Floor Exercise apparatus.

According to one aspect of the present invention there is provided a portable electrical stimulation apparatus for treatment of incontinence disorders, comprising;

one or more electrodes for applying one or more electrical stimulation signals to a patients body;

a signal generator for generating the electrical stimulation signal(s);

one or more conductive leads for connecting the signal generator to the electrode(s), to deliver the electrical stimulation signal to the electrode(s); and

a power supply,

characterised in that the apparatus includes an instruction storage means or a programming means for imparting a set of instructions to the signal generating means, the signal generating means being responsive to the instruction storage means or programming means so that the generated signal adopts signal waveform characteristics selected in accordance with said set of instructions.

Preferably at least one electrode is applied in the vaginal or anal region, and at least one electrode is a surface electrode to be applied to a surface of the patients skin.

Preferably the waveform characteristics of the electrical stimulation signal are not alterable by the patient, the waveform being determined from normal neuronal activity of the patient and applied so as to superimpose the normal neuronal activity.

Preferably said instructions comprise instructions on the selection of one or more of the following signal waveform characteristics:

pulse geometry type;
pulse width magnitude;
pulse train frequency;
pulse envelope type;
pulse envelope duration;
pulse envelope duty cycle;
treatment time;
signal intensity.

Preferably the pulse envelope duration is in the range 1 to 100,000 microseconds.

Preferably the pulse train frequency is in the range 200Hz to 5MHz.

Preferably the envelope duty cycle is in the range 1 to 99%.

Preferably the number of pulses per each envelope is in the range 1 to 20,000.

Preferably the pulse envelope is of a sinusoidal, square wave or saw tooth wave type.

Preferably the frequency with which the envelope occurs is in the range 0.1 to 2,000Hz.

The pulse envelope may occur at a time in the duty cycle, which is random between successively generated envelopes.

Preferably the instruction storage means is a smart card.

Preferably the programming means is a personal computer.

Preferably the apparatus has a data logging means for recording generation of the electrical stimulation signal, so as to provide a record of how often the electrical stimulation signal has been generated.

According to a second aspect of the present invention there is provided an electrode characterised by being adapted to attach to the surface of a perineal region, and an electrode characterised by being attached to the lower sacral region. Said electrodes comprise a flexible conductive substantially sheet material.

Preferably, said electrodes are adaptable for use in the treatment of incontinence. The flexible conductive sheet material preferably comprises a woven or knitted cloth.

Said woven or knitted cloth may contain conductive fibres of stainless steel, gold or other electro plated precious metals.

Preferably said electrode further comprises a waterproof backing.

Preferably said electrode is attachable to a perineal region using a conductive adhesive gel.

Said electrode may have a stud fixing.

Preferably, said electrode has a pigtail type electrical connector.

Preferably a length of said electrode is in the range 20 to 100 millimetres, and is suitably in the range 40 to 60 millimetres.

Preferably a width of said electrode is in the range 10 to 60 millimetres, and is suitably in the range 20 to 40 millimetres.

The shape of the electrode may be such that it has one or more concave perimeter portions. The electrode may have one or more convex perimeter portions.

Preferably, the electrode has an electrical plug connection, and may have an electrical connection lead.

The electrode may have an elongated centre portion of a first width and one or more protruding end portions of a second width, wherein said second width is greater than said first width.

According to a third aspect of the present invention, there is provided an electrode which is adapted to be insertable into an anatomical cavity or tract, said electrode comprising a plug of a substantially expandable and/or compressible material.

The flexible and compressible construction of the internal electrode is such that it can be compacted into tampon form for ease of insertion, hygiene and comfort. Once in place, the tampon will expand and provide electrical contact with the vaginal/anal walls.

Said material may be a foam material.

Said material may be a polyvinyl formal foam (PVF) material.

Said material may be a paper or cotton material.

Said electrode may further comprise a conductive sheath surrounding at least partially said plug.

Said conductive sheath may be of a woven or knitted cloth.

Said electrode may further comprise a conductive lead adapted for carrying a drive signal to said conductive material and for removing said plug from said cavity.

Said electrode may be adapted for insertion of a rigid support member to support the electrode during insertion of said electrode into said cavity or tract, said support member being removable once said electrode is deployed therein within said cavity or tract.

Said electrode may be adapted for deployment in said cavity or tract by insertion of a hollow tubular applicator containing said electrode in compression, in to said cavity or tract, followed by subsequent removal of said applicator from the cavity or tract, allowing expansion of said electrode within said cavity or tract.

According to a fourth aspect of the present invention there is provided a tampon electrode for insertion into the vagina or anus of a patient, the electrode comprising:

an outer sheath having a conductive outer surface for imparting an electrical stimulation signal to the vaginal or anal wall; and

a conductive lead for supply of the electrical stimulation signal to the electrode;

characterised in that the outer sheath is expandable and contractible such that the sheath can be inflated or deflated whilst in position in the vagina or anus.

Preferably the electrode has a rigid inner member around which the outer sheath is arranged, such that when the electrode is in the deflated condition, the rigid inner member lends the electrode sufficient rigidity so as to enable the electrode to be pushed into the vagina or anus for insertion therein.

Preferably the electrode has a fluid supply tube connected thereto for delivery of a pressurised fluid to the electrode for inflation thereof.

Preferably the electrode is inflatable by an increase in air pressure within the outer sheath.

Preferably the outer sheath is of an elastic material.

Preferably said elastic material is a silicon rubber.

Preferably the conductive outer surface comprises a woven or knitted conductive cloth attached to the outer sheath.

According to a fifth aspect of the present invention there is provided a sensing apparatus for sensing the condition of muscles in the vaginal or anus region, characterised by comprising:

a tampon electrode for insertion into the vagina or anus, the tampon electrode capable of transmitting a pressure signal in response to an increase in pressure exerted on the electrode by the vaginal or anal muscles;

a pressure sensor means for sensing the signals, the pressure sensing means producing an output dependent on the pressure exerted on the electrode by the vaginal or anal muscles.

Preferably the pressure signal is a pneumatic signal or an hydraulic signal, generated in response to pressure exerted on an expandable or contractible electrode.

Preferably the electrode is inflatable and there are provided means for inflating the electrode.

The electrode may have a conductive outer surface for applying an electrical stimulation signal to the vaginal or anal region, and the sensing apparatus includes a signal generator for generating the electro-stimulation signal, and may include a conductive lead for delivery of the electrical stimulation signal from the signal generator to the electrode.

Preferably the apparatus has an electro-myographic or perineometer sensor, which receives an electrical signal from the conductive outer surface of the electrode via the conductive lead, the signal generator being arranged

to produce an electro-stimulation signal in response to an output from the electro-myographic or perineometer sensor.

The apparatus may be adapted for use as a means of facilitation of muscles in the vaginal region or anal region.

Preferably the apparatus has a display and a data recording means.

The present invention may provide a multiplexed combination of transcutaneous surface electrodes and/or internal vaginal/anal electrodes. The electrical characteristics of the said electrodes are provided by woven or knitted conductive fabric which ensures uniform current distribution and maximum comfort and hygiene.

The invention may provide a pulse generator which is convenient and simple for the patient to operate. Preferably, the pulse generator incorporates a data logging system to record patient compliance to treatment. Multiplexed pulse parameters can be preselected by the clinic for specific treatments by insertion of the specially preprogrammed Smart Cards such as those using the PCMCIA Interface Standard.

Treatment parameters may be down loaded from a PC into an integral memory using specially prepared software which initiates the specific parameters according to a patient's case history and symptoms. Preselected

parameters loaded into the pulse generator are not available to or adjustable by the patient and which ensures strict compliance to the specific treatment regime.

Pulsed currents are delivered by the pulse generator, via the transcutaneous conductive surface electrodes which have specific anatomical placement to stimulate the dorsal and perineal branches of the pudendal nerve as they arise above the lower facia of the uro-genital diaphragm.

Pulsed currents may also be applied directly to the fibres of the levator ani muscle through the vaginal or anal walls using the tampon electrode. Pulsed currents may also be applied via a combination of the tampon and the surface electrodes to direct the current to specific muscles/nerve groups.

The present invention may provide for such pulsed currents to be supplied in variable frequency envelopes which are concomitant with normal neuronal activity determined from similar, but healthy nerve/muscle groups. The effect of such specific treatment currents is to re-establish neuronal motor and sensory control and to increase the population and fatigue resistance of the type I postural muscle fibres which are responsible for uretheral and anal closure.

Provision is also made within the preset parameters to strengthen the type II muscle fibres responsible for additional effort, support and reflex closure during physical stress conditions.

The present invention may also provide for an inflatable tampon electrode which can be used A) to apply the preset treatment parameters through the vaginal and/or anal walls, or B) as an electromyographic perineometer sensor to measure improvement achieved by the treatment and to provide encouragement for the patient to continue, or, C) as a means of Facilitation to provide a combined voluntary and F.E.S induced muscle exercise programme.

Any of the said tampon electrodes can be used solely or in combination with the cutaneous electrodes.

The invention includes a portable electrical stimulation apparatus comprising;

a signal generating means for generating an electrical signal; and

a preset instruction means, or a preset programming means, for imparting instructions to the signal generating means,

wherein the signal generating means is responsive to the programming means such that the generated signal can adopt characteristics selected in accordance with said instructions.

Preferably, said programming means comprises a memory storage device pre-programmed with said instructions.

Preferably, the memory storage device is detachable from said signal generating means.

Preferably, the apparatus has a plurality of said memory storage devices, each substitutable for one another.

Each individual said memory storage device may be pre-programmed with a different set of instructions to each other memory storage device. Preferably, the apparatus further comprises a signal processing means for producing an electrical drive signal in accordance with any of said instructions. Said memory storage device may be permanent within the apparatus and can be programmed via a personal computer using software routines which generate the said parameters from data input in respect to patient history and symptoms. The said software may comprise user friendly windows with relevant prompts for every aspect of treatment to be considered. A user option is provided to allow final parameter adjustment within predetermined limits. Thus a set of said memory storage devices may be provided, each containing instructions to the signal generating means for generating a signal suitable for treatment of a particular disorder.

The apparatus may have a patient- adjustable means of varying the intensity of an electrical drive signal to an electrode.

According to a further aspect of the present invention, there is provided a portable electrical stimulation apparatus comprising a drive signal generation

means and recording means for recording data regarding operation of the drive signal.

Said recorded data may include the frequency and/or duration of a time period in which said drive signal is actively conducted through living tissue. This may provide a strict compliance record of stimulation applied to the body. Said recording will not register if electrodes become detached or short circuited.

Said recording means may be interrogatable to display parts of said data. Said recording means may be interrogatable by a personal computer via a data port, said data port comprising part of the apparatus.

Said recording means may also be embodied within a Smart Card or Flash Card with random access memory (RAM) or non volatile memory. Said storage device will preferably be portable and be able to transmit and receive stored data berween a personal computer and the signal generator.

According to another aspect of the present invention, there is provided an electrode which can be attached to another part of the external anatomy such as a buttock. This indifferent electrode would preferably be used with monophasic or a symmetrically balanced pulse geometry where stimulation at the indifferent is unimportant to the treatment.

As such, this electrode may be of arbitrary shape and size, but will preferably be of twice the conductive surface area to that of the perineal electrode to provide a wider dispersal of the current at the indifferent electrode position over the sacral plexus.

Said indifferent electrode is preferably of specific shape and size to mould comfortably over the sacral spine, spinous processes, S2, S3 and S4. Said position is preferable to provide stimulation using balanced byphasic pulse geometry over the sacral nerve routes from where the urinary and faecal control nerves originate.

The invention provides for an electrode adapted to be insertable into an anatomical cavity or tract, said electrode comprising a core of a substantially expandable and/or compressible material.

Said material is preferably substantially deformable and resilient.

Preferably, the electrode further comprises a conductive sheath surrounding at least partially said core.

Preferably, said conductive sheath is of a woven or knitted fibre, for example stainless steel, gold or other electro-plated precious metal.

Preferably, the tampon electrode further comprises a conductive lead adapted for carrying a drive signal to said conductive material and for removing said electrode from said cavity.

The core may have a hollow passage for the insertion of a rigid member for supporting the core during insertion into the cavity or tract.

Said tampon electrode may have a first said conductive sheath and a second said conductive sheath. said sheaths being electrically isolated from each other. said sheaths having respective first and second electrical connection means thereto.

Said first and second sheaths may be driven by respective first and second driving signals.

Said first and second driving signals may be substantially identical or may be substantially dissimilar to each other.

The invention includes use of a said tampon electrode having first and second conductive sheaths in F.E.S. treatment of incontinence.

The invention provides for a plug having a core of a resilient deformable material for insertion into a human vaginal or rectal tract.

Preferably, said core material of said electrode or plug has a Shore hardness of below 45.

Suitably, said material has a Shore hardness of less than 30.

Said material may be a foam material, for example a polyvinyl formal foam (PVF) material. Said material may be a paper or cotton material.

An electrode or plug according to the fourth or fifth aspects may be adapted for insertion of a rigid support member to support the electrode during insertion of said electrode into said cavity or tract, said support member being removable once said electrode is deployed therein within said cavity or tract.

A said electrode or plug according to the fourth or fifth aspect may be adapted for deployment in said cavity or tract by insertion of a hollow tubular applicator containing said electrode in compression into said cavity or tract, followed by subsequent removal of said applicator from the cavity or tract, allowing expansion of said electrode within said cavity or tract.

Preferably an electrode and/or plug according to the fourth or fifth aspect has a length in the range 30 to 100 millimetres.

Suitably, said length is in the range 45 to 65 millimetres.

Preferably, the electrode and/or plug has a width or diameter in the range 10 to 40 millimetres.

Suitably, the width is in the range 20 to 30 millimetres.

The invention provides for an inflatable tampon electrode. Said inflatable tampon electrode may have a gossamer, non-conductive outer sheath. Said outer sheath may be a silicon rubber. Said outer sheath may incorporate an integral conductive band. Said conductive band may be a substantially sheet material.

Said sheet material may be of woven or knitted conductive cloth. Said conductive cloth may be woven or knitted fibre, for example stainless steel, gold or other electro-plated precious metals. Said conductive cloth may extend internally to form the connecting means to a pulse generating apparatus. Said connecting means may also provide a means of obtaining electromyographic (EMG) readings and recordings.

Said connecting means will pass through a semi-rigid tube which may be used to insert the tampon prior to treatment. Said semi-rigid tube will provide a means to pass air into the outer flexible sheath such that the outer sheath may be inflated until it is in contact with the internal walls of the patients body cavity. Said air tube and electrical connection is preferably connected to a monitoring and stimulating apparatus, preferably incorporated into the pulse generator.

Said apparatus may comprise an air pump to inflate the tampon, and a pressure sensor to monitor internal air pressure and to cut off the air supply to the tampon when a predetermined level of air pressure is reached. Said sensor may determine a volumetric inflation required to attain a resting tone pressure of the muscles surrounding the inflatable sheath and may detect any increase caused by contraction of the surrounding muscle. Such a measurement may indicate a patient's progress and improvement due to the main stimulation treatment.

Said sensor may be used to facilitate stimulating pulses in response to pressure increase due to voluntary muscle contraction. Said stimulating pulse will cause further muscle contraction and further aid strengthening. Through this facilitation, the patients voluntary muscle strength will be enhanced by muscle stimulation. Said pulse parameters may be any of those previously described. Said apparatus may store data in a memory for later analysis. Said apparatus may provide a visual display which a patient may use to work to a daily exercise/facilitation routine with specified targets and visual achievements.

The invention includes a compilation of an electro-stimulator apparatus as above, a selection of stimulator electrodes as above, a selection of programming modules each programmed for a different type of treatment, a plurality of treatment instruction cards corresponding with the modules and giving instructions for the administration of treatment by the patient and/or

clinician in accordance with the module, and an instruction guide on the use of the apparatus, which may also be incorporated in the Smart Card.

The invention includes a method of treatment of incontinence using electrical stimulation of a perineal region by a flexible substantially sheet material electrode.

The invention includes a method of treatment of incontinence using Pelvic Floor Exercises and Bio feedback using an electrode or plug as described in the fourth or fifth aspects.

The invention includes a method of monitoring a patients' progress, and determining an improvement in pelvic floor tone and strength.

Description of the Drawings

For a better understanding of the invention, and to show how the same may be carried into effect, reference will now be made, by way of example, to various specific embodiments of the invention as shown in the accompanying diagrammatic drawings, in which:

Figure 1 shows a portable drive module according to a specific embodiment of the present invention, for driving an electrode;

Figure 2 shows a schematic circuit diagram of the drive module;

Figure 3 shows in plan view a first cutaneous electrode pad according to a another specific embodiment of the present invention;

Figure 4 shows in plan view a second cutaneous electrode pad according to a further specific embodiment of the present invention;

Figure 5 shows in plan view a third cutaneous electrode pad in accordance with yet another embodiment of the present invention;

Figure 6 shows in plan view an electrode for positioning on the sacrum of a patient, according to another embodiment of the present invention;

Figure 7 shows an electrode for positioning in the perineal region, according to another embodiment of the present invention.

Figure 8 shows a construction of the embodiments of Figures 3 to 7;

Figure 9 shows one way of positioning the sacral electrode of Figure 6 on a patients skin;

Figure 10 shows one way of positioning the perineal electrode of Figure 7 on a patients skin;

Figures 11 to 19 show various prior art pulse geometry components;

Figure 20 shows part of one example of an electrical stimulation drive signal according to the present invention:

Figure 21 shows as an example according to the present invention, a part of an electrical stimulation drive signal in the form of a preprogrammed pulse train;

Figure 22 shows as an example according to the present invention, a part of an electrical stimulation drive signal having a bi-phasic pulse train envelope;

Figure 23 shows as an example according to the present invention, a form of an electrical stimulation drive signal having a bi-phasic pulse train and a pulse train envelope which is modulated;

Figures 24 to 26 show the preselected pulse geometry delivered in various pulse envelopes timed over predetermined execise and relax periods. the voltage intensity in the initial and final time periods within each exercise and relax phase may also be ramped up or down for additional patient comfort.

Figures 24 shows as an example according to the present invention, a part of an electrical stimulation drive signal having uniform fixed rate envelopes;

Figure 25 shows as an example according to the present invention, a form of electrical stimulation drive signal having a randomly generated envelope;

Figure 26 shows as an example according to the present invention, a form of electrical stimulation drive signal having sequentially generated envelopes;

Figure 27 shows a first insertable electrode for internal use, according to an embodiment of the present invention;

Figure 28 shows a second insertable electrode according to another embodiment of the present invention;

Figure 29 shows a third insertable electrode according to another embodiment of the present invention;

Figure 30 shows a fourth insertable electrode according to another embodiment of the present invention;

Figure 31 shows a fifth insertable electrode according to another embodiment of the present invention.

Figure 32 shows a construction of part of an insertable electrode according to an embodiment of the present invention;

Figure 33 shows an inflatable electrode according to a specific embodiment of the present invention; and

Figure 34 shows a sensing apparatus according to a specific embodiment of the present invention.

Best Mode for Carrying out the Invention

An electro-stimulation apparatus according to a specific embodiment of the present invention comprises a drive module and a stimulation electrode arranged to be driven by the drive module.

Referring to Figures 1 and 2 of the accompanying drawings, a drive unit 1 comprises a portable case 2 which contains an electric battery power supply, 4, and electronics (not shown in Figure 1). The drive unit has a detachable instruction storage or programming means such as a smart card 3 and further comprises a clip for attaching the drive unit to an item of clothing, for example a belt.

The smart card 3 is attachable to the electronics of the drive unit 1 via a connection socket 5 and is detachable such that it can be replaced by a substitute Smart card.

The drive unit further features an intensity control 13 for controlling the intensity of the drive signal to the stimulator electrode, the intensity control being of a type which can be altered by the patient, and an indicator lamp 14 to indicate when the drive signal is operating and/or whether the battery is charged. A liquid crystal display (LCD) may also be provided to show the status of the device.

Referring to Figure 2 of the accompanying drawings, a schematic diagram of the electronics of the drive unit of Figure 1 is shown. The electronics comprises the socket 5 for accepting the Smart Card 3, a battery power supply 6 for supplying power to the electronics, a pulse generator 7, an output pulse shaper 8 for modifying the output of the pulse generator 7 and outputting a drive signal, a plurality of output sockets 9 connected to the output pulse shaper 8 and providing an output path for the drive signal, an intensity control 13, which is, for example a thumb wheel variable resistor, a real time logger 10 for recording parameters of the output of the pulse generator and/or drive signal and an external connector 11, for example a serial port through which the real time logger 10 can be interrogated periodically using separate interrogation equipment, for example a personal computer, and the battery charge/signal output indicator 14.

The output socket 9 is connectable to a stimulator electrode, which is driven by the drive signal via an output electrode lead 12 from the drive unit.

The electrode lead 12 is preferably of a high flex material such as silicon rubber, having standard 2mm plug pins or press-stud type fasteners for connecting to the stimulator electrode.

The Smart Card may be either pre-programmed or programmable using a standard PC. The smart card module could be replaced by some other instruction storage or programming means, e.g. an audio cassette, or an internal ROM programmable externally of the drive unit. Hereafter, for convenience, the instruction storage or programming means will be referred to as a Smart card.

In use, the drive module operates as follows. The pulse generator, produces a pulse signal in response to programmed instructions stored in the smart card 3. The pulse signal is then modified by the output pulse shaper 8 in accordance with the instructions stored in the Smart card. A drive signal appears at the output of the pulse shaper, on the output lead 12, and is supplied to the output socket 9 connected to the stimulation electrode.

Each smart card may be supplied either pre-programmed or programmable using a standard personal computer. Each pre-programmed smart card is clearly marked with the parameters of the drive signal which the card is programmed for producing, together with the type of therapeutic treatment to which these parameters relate. For example, a smart card may be marked with the following information, and programmed accordingly with

instructions for generating electrical stimulation drive signal having corresponding waveform characteristics.

Treatment, URINARY STRESS INCONTINENCE

Pulse geometry - square biphasic
Pulse width - 200 μsecs
Pulse envelope frequency - Random 5 - 40 Hz
Pulse envelope - 100 msecs
Exert/relax - 8 sec cycle 50% duty cycle
Treatment time - 2 hours
Intensity - 0 - 30 Ma.

In other Smart cards for other treatments, variations upon the above drive signal characteristics may be made. For example any of a number of drive signal characteristics may be varied.

The real time logger 10 records details of the pulse signal output from the pulse generator 7 through normal biological body impedance. Stimulation pulses generated during electrode disconnection or short circuit will not register on the data logger or Smart Card. Compliance of the output drive signal can be monitored and checked against treatment prescribed by a clinician. The recorded data shows whether a treatment has been administered on a regular basis, without any parameters of the drive signal being tampered with by the patient.

In use in a clinical situation, a complete electro-stimulator apparatus comprises a selection of stimulators, a selection of modules each programmed for a different type of treatment, treatment instruction cards corresponding with the modules and giving instructions for the administration of treatment by the patient and/or clinician, a battery recharger, (where required) and a full instruction guide on the use of the apparatus.

Figures 3 to 7 of the accompanying drawings show various embodiments of transcutaneous electrode pads suitable for perineal application. Such electrodes are suitable to be driven by the drive unit described with reference to Figures 1 and 2.

The electrode pads are constructed from woven or knitted electrically conductive cloth, mounted on a thin flexible and waterproof material and coated in a self-adhesive conductive gel. The conductive gel is of a known prior art type, and in one version is formulated to be adjustable in adhesive strength by the addition of water.

The first embodiment electrode 50 shown in Figure 3, a stud fastener 51 and a pigtail cable 52 having a socket 53 for connection to for example the output socket 9. Where a pigtail connection is used the conductive elements of the cable 52 may be extensions of the woven material of the electrode 50. Connection of the conductive elements to the plug 53 may be by moulding the elements into the plug, by sewing the elements into the plug after moulding, by adhesive bonding using a conductive adhesive or by ultrasonic welding.

Similarly, the conductive elements of the cable 52 may be adhesively bonded to, or ultrasonically welded to, or sewn into the woven material of the electrode 50.

The electrode is shaped as shown, having an elongate strip 60 of a first width having projections 62 of a second width at each end. A perimeter 63 has one side 64 which is convex in shape, and one side 65 which is concave.

A preferred maximum length for the electrode shown in Figure 3 is of the order 50mm, and preferred widths are in the range 20 to 40mm, preferably in three sizes of widths 20mm, width 30mm and width 40mm.

Referring to Figure 4, a second embodiment electrode has a plug 51 or a pigtail 52, 53 similarly as above, and is of similar maximum dimensions as the first electrode.

A third embodiment electrode as shown in Figure 5, is of a "kidney" type shape, has either a plug 51 or pigtail 52, 53 and is preferably of external maximum dimensions of the same order as the electrode of Figure 13.

Although the above dimensions are preferred, it is anticipated that some variation in dimensions of up to plus or minus 100% may suit the wide variety of naturally occurring sizes and shapes of the perineal body.

Referring to Figure 6 of the accompanying drawings, an electrode suitable for fitting to the sacral region is shown. The electrode is of knitted or woven conductive cloth, similar to the above mentioned electrode, and is of a generally truncated triangular shape in plan view. The electrode has a base width of around 67mm, a height of around 70mm and a apex plateau region 200 of width around 15mm. The plateau region has a dipped portion for placement of a finger to aid in positioning of the electrode over the sacral spinous processes of S2, S3 and S4. The electrode is provided with a pigtail electrical contact lead 201 of length around 54mm, terminating in a plug connector 202.

Referring to Figure 7 of the accompanying drawings a surface electrode 203 suitable for fitting to the perineal region comprises a sheet of conductive woven or knitted material in the shape of an hour glass 205, having a length of around 50mm and a width of around 40mm. The neck of the hour glass shaped electrode is preferably of width around 16mm, and a pigtail lead of length around 92mm is provided. Preferably, the pigtail lead is attached at the side of the electrode as shown in Figure 7, for hygiene and ease of fitting.

Referring to Figure 8, a structure of an electrode pad is shown. The pad comprises a woven or knitted conductive cloth 80, coated in a conductive adhesive gel 81. The adhesive gel may be of a known type. The cloth 80 is coated by a water proof backing 82, which is for example a plastics sheet material. The water proof backing is attached to the cloth by an adhesive layer 83. A conducting wire 84, in the form of a pigtail lead is electrically

and physically attached to the cloth 80. A drive signal is transmitted along the pigtail to drive the electrode. The electrode pad has a press-stud 85, which may be used for aiding placement of the pad using a strap or the like. The stud may be electrically conducting and contact the cloth 80 such that a drive signal may be supplied via the stud in addition to or in alternative to the pigtail lead 84.

Referring to Figure 9 of the accompanying drawings, placement of the sacral surface electrode of Figure 8 is shown schematically, in combination with a further surface electrode 300 placed on a buttock of the patient, the further electrode being an indifferent electrode.

Preferably the sacral surface electrode is positioned over the sacral spine S2 - S4. Placement of the indifferent electrode is optional.

Referring to Figure 10 of the accompanying drawings, the perineal surface electrode as described with reference to Figure 8, is shown positioned over the perineal body of a patient to provide stimulation to the dorsal and perineal branches of the pudendal nerve 301. The sacral electrode 302 is also shown in position.

Any of the above electrodes may be reusable or disposable.

Use of the apparatus described with reference to Figures 1 to 10 will now be described, referring also to Figures 11 to 26.

In use, for treating urinary incontinence, one or more of the above electrodes are deployed over a perineal body between (in a female) the vagina and the anus. It is important that the electrode remains firmly in position during normal movement and is flexible enough to accommodate such movement. The use of a knitted or woven conductive material with a conductive adhesive gel in an electrode of shape specifically adapted for the perineal region may provide the necessary comfort and secure fixing to allow treatment of incontinence by a cutaneous electrode to be acceptable to the patient.

The electrical stimulation drive signal may be constructed as a combination of one or more signal per pulse geometries. Examples of such signal pulse geometries which may be selected according to instructions on the smart card are shown in Figures 11 to 19. For example Figure 11 shows a simple Galvanic type wave form. Figure 12 shows a simple sinusoidal waveform. Figure 13 shows a square monophasic waveform. Figure 14 shows a square waveform. Figure 15 shows a square bi-phasic waveform. Figure 16 shows a pulsatile (asymmetric balanced) wave form. Figure 17 shows a Faradic waveform. Figure 18 shows a monophasic sawtooth spike wave form, and Figure 19 shows a bi-phasic sawtooth spike, wave form.

The Pulse Width may be selectable from, for example, any one of 80, 160, 200, or 320 μsec widths. The Pulse Envelope frequency may be selected from any one of three types. Type one is a regular fixed frequency rate, for example 10Hz. Type two is a sequential rate rising or falling from a preset

starting frequency to a preset final frequency. Type three is a randomly generated frequency rate with pulse separations occurring randomly between preset start and end frequencies. The pulse envelope duration may be selected from a range including for example 100, 250, 500, 750, or 1,000 μsecs. The Exercise/Relax cycle is similarly variable and the initial and final intensity voltages may be adjustable to provide a smooth ramp up and down for patient comfort. The overall treatment time is variable and the intensity may be selectable from the following ranges: 0 - 30mA, 0 - 60 mA, or 0 - 100mA.

Referring to Figure 20 of the accompanying drawing, an example of a portion of a specific output drive signal waveform in accordance with specific pre-programmed instructions is shown. The example shown comprises a square monophasic waveform having a pulse burst duration of 100 μsecs and a frequency of 2 Khz. The pulse width is 80 μsecs and the period between bursts is 99 ms. The intensity (the height of the pulse in Figure 11) is adjustable by the patient in the range 0 - 60mA. Other portions of the drive signal waveform may have a frequency in the range 1Hz to 2KHz.

Referring to Figure 21 of the accompanying drawings, a typical preprogrammed bi-phasic pulse train is shown. The pulse train comprises a first pulse 500 of duration time T1, an inactive period 501 of duration time T2, a second pulse 503, of an opposite sense to the first pulse 500, and of duration time T3, and a second inactive time T4, the second inactive time being variable according to the frequency selected. The times T1, T2 or T3

are variable but typically may be T1=200 μsecs, T2=100 μsecs, T3=200 μsecs.

Referring to Figure 22, a preferred form of bi-phasic pulse is shown in an envelope train. The envelope duration is preferably in the range 100 to 1,000μsecs, and N pulses per envelope are provided, N preferably being in the range 1 to 1,000. The envelope frequency FR2 can be sequential, random or fixed and is typically in the range 0.1 to 100Hz. The period between repetitions of pulse packets, FR1 typically corresponds to a frequency of 500 to 5,000Hz.

Referring to Figure 23, a pulse train having a modulated envelope is shown. The modulation of the pulse train envelope can be any suitable shape. The duty cycle of the envelope, within the envelope period defined by the envelope frequency FR2, is preferably in the range 1 to 99%.

Referring to Figure 24 of the accompany drawings, an example of a uniform (fixed) rate envelope is shown. A preselected pulse geometry of pulses being spaced apart by 2 μsecs, with a preselected pulse geometry of either a monophasic or bi-phasic, and either a square or random characteristic is selected.

Figure 25 shows a random generated envelope sequence in which pulses within the envelope are randomly spaced apart from each other, in this example by a period between a first and second pulse being 2 μsecs, the

period between the second and third pulse being randomly selected as 10 μsecs, the period between the third and fourth pulse being randomly selected as 6 μsecs, between the fourth and fifth pulse the time is randomly selected as 2 μsecs, and between the fifth and sixth pulse the time is randomly selected as 4 μsecs. In a succeeding pulse envelope, the times between the pulses within the envelope are randomly selected again, and are different from those in the first envelope shown.

Use of a randomly generated pulse train within a fixed pulse envelope may have an advantage that the human body does not become acclimatised to the particular form of treatment. The patients body may maintain its response to the treatment, which has no predictable pulse pattern within the pulse envelope, over an indefinite period, without significant loss of effectiveness.

Referring to Figure 26 of the accompanying drawings, a set of sequentially generated envelopes are shown in which the exercise phase (i.e. the period occupied by the pulse envelope), and the relax phase are variable. This is equivalent to varying the position in time of the pulse envelope within the duty cycle. In the example shown, within the pulse envelope, the pulses are ordered such that the second pulse is spaced from the first pulse by a time of 2 μsecs, the time elapsed between the second and third pulses is 4 μsecs, the time elapsed between the third and fourth pulses is 6 μsecs, and the time elapsed between the fourth and fifth pulses is 8 μsecs. This pattern is repeated in successive sequentially generated envelopes.

Hereinabove, Figures 24 to 26 have shown the exercise/relax cycles with a constsnt amplitude at start and finish. This may be replaced with a gradual ramp up/down over a preselected period similar to that shown in Figure 24.

Various other electrodes, of the insertable type, will now be described.

Referring to Figure 27 of the accompanying drawings, a first insertable electrode comprises an inner core moulded from a resilient and deformable material such as a foam, or paper/cotton fibre 100 and an outer conductive sheath 101 of knitted or woven conductive fibre, for example stainless steel fibre, or metallized plastic fibre. The outer conductive sheath surrounds the inner core 100. Individual fibres of the outer conductive sheath are gathered into a thread 102 and connected via a crimp connection 103 to a flexible pigtail connector wire 104 of, for example, silicon rubber coated wire. The flexible pigtail connector wire has at one end a plug 105 for connection to a drive unit.

The material of the inner core 100 and the outer conductive sheath 101 are deformable to allow compression and insertion of the electrode into a hollow tubular applicator (not shown). A suitable core material has a Shore hardness of below 45, and is deformable enough so as to be compressed to 75% or less of its unrestricted size. In an electrode of dimensions suitable for insertion into a vaginal or rectal tract, a surface of the foam is preferably depressible by at least 1.5mm.

Biocompatible fibres may be used in the construction. For example Biocompatible Polyvinyl Formal (PVF) foam, cotton or paper materials.

The electrode may be manufactured as a single moulded flexible conductive foam or as a moulded PVF foam plug surround by flexible conductive woven or knitted cloth sheath. In this latter embodiment, the sheath may be incorporated during the moulding phase of manufacture or may be fitted after moulding.

The electrode may alternatively be manufactured as a moulded PVF foam as above, but with an inner plug manufactured from fibrous paper or cotton material.

In use, the applicator, containing the electrode, is inserted into either a vaginal or anal tract, to position the electrode therein. The applicator is then withdrawn, without moving the electrode. Once released, the foam material of the electrode expands to provide close contact with an internal wall of the vaginal or anal tract. A lubricating gel may be used during insertion and/or extrusion of the applicator to aid deployment. The gel may be conductive.

The electrode may be washable or disposable.

Referring to Figure 28, a second insertable electrode comprises an elongate substantially cylindrical core of a resilient deformable material 100

as aforementioned with reference to Figure 27, having a tubular band of conductive material 101 which surrounds and constricts a mid portion 109 of the core. At either end of the band, portions of the core 110, 111, which are unrestrained by the band 101 relax to adopt an uncompressed diameter greater than the diameter of the constricted mid portion of the core 109.

The mid portion 109 of the core may be further compressible by compressing the conductive material 191, but is restricted from substantial expansion to a fully relaxed state by the band 101.

The tubular band is of length in the range 15 to 20mm, the overall length of the core being suitably in the range 50 to 60mm and the relaxed diameter of the core being in the range 20 to 30mm. These dimensions may be varied to accommodate natural anatomical variations.

The second electrode has an hollow tubular passage 108 centrally, for accommodating a rigid rod centrally in the core. Using this rod, the electrode may be pushed into the tract without the need for an enclosing applicator as described with reference to Figure 18. In this mode of deployment, the end portions 110, 111 of the core, and/or the mid portion 109 may be squeezed during insertion, and then expand when in place in the tract.

However, the embodiment is not restricted to this mode of deployment and may be inserted in a hollow applicator as aforementioned with reference to Figure 18, and may retained in the tract during removal of the applicator

by the insertion of the rod in the hollow passage 108. The rod is subsequently removed.

The second insertable electrode has a contact lead 104 and plug 105 for making electrical connection to the conductive material 101 and for use in removing the electrode from the tract.

Referring to Figure 29, a third insertable electrode is of similar construction to the second electrode, but, a tubular band 130 of conductive material of length in the range 6 to 12mm is provided.

Referring to Figure 30, a fourth insertable electrode is of similar construction to the above mentioned first insertable electrode, of Figure 18, however, in the fourth insertable electrode, a hollow passage 108 is provided in the core 131 for insertion of a rigid rod, similarly as described with reference to the second insertable electrode.

Referring to Figure 31, a fifth insertable electrode comprises a core of flexible material 100, similarly as described with reference to Figure 19, and first and second tubular bands 150, 151 each of a conductive material as described hereinabove with reference to Figures 18 to 21. Each conductive band 150, 151 is connected to a respective first and second conductor leads 152, 153, in a manner as hereinabove described.

Preferably, the conductive bands are each of length 6mm or thereabouts, and separated by a distance of 8mm, although these dimensions and lay outs are not restrictive and may be varied. During treatment, the inflatable tampon electrode may be used periodically to monitor progress and provide encouragement for the patient to continue.

The fifth electrode may be deployed as previously described hereinabove with reference to Figure 28.

In use, the fifth electrode may be electrically driven via the first and second leads 152, 153 by respective first and second drive signals. The first and second drive signals need not be identical, and preferably have different parameters. Such an electrode may be suitably useable in FES treatment.

Referring to Figure 32, a structural portion of an insertable electrode is shown. Such a structure may be incorporated into any one or more of the insertable electrodes as described with reference to Figures 27 to 31 as hereinabove described.

The structure comprises a core of foam material 100, such as hereinabove described, an electrically insulating backing material 140, for example a sheet material, an adhesive layer 141, and a conductive fibre material 142. The insulating backing material and adhesive layer are sandwiched between the conductive material and the core.

A connecting lead 143, in the form of a pigtail wire, is incorporated into the structure, making electrical contact with the conductive material 142. The connection is of sufficient strength to enable the insulating electrode to be pulled using the connecting lead, without the connecting lead coming loose from the structure. Additionally, the lead may be woven into or otherwise attached to the conductive fibre 142, similarly as herein described with reference to cutaneous electrodes.

Referring to Figure 33 of the accompanying drawings, an inflatable tampon electrode for insertion into the vagina or anus of a patient is shown, the electrode having an outer sheath 600, of a rubber silicon material, the outer sheath being inflatable or deflatable by air which is pumped in through a delivery pipe 601 and a rigid internal member 602, and a woven or knitted conductive cloth 603 bonded to the outer surface of the rubber sheath 600. The conductive sheath is connected to external sensing apparatus by an electrically conductive lead wire 604 which runs through the centre of the rigid member and the hollow air delivery pipe 601.

Referring to Figure 34 of the accompanying drawings, the other end of the delivery pipe 601 and connecting lead 604 enter a sensing apparatus 700. The sensing apparatus comprises a pressure sensor 701, a pulse generator 702, an electromyographic sensor 703, an air compressor 704, and a display and data recorder 705.

The tampon electrode of Figure 35 and the sensing apparatus of Figure 34 are used in various modes as follows. Firstly, the air compressor is run continuously to inflate the inflatable tampon electrode of Figure 35. A patient is encourage to squeeze the tampon electrode. and changes in air pressure are detected by the pressure sensor 701 and displayed by the display and data recorder 705. Thus a measure of the strength of a patient's muscles can be determined by the read out on the display and data recorder 705. Alternatively, the patient can be asked to squeeze the electrode, and the number of strokes of the air compressor counted in order to reach a predetermined pressure. This number of strokes will also give a measure of the condition of the patient's muscles.

In a facilitation mode. the patient is encouraged to squeeze the electrode. which is inflated by the air compressor 70, when squeezing of the electrode is detected by either a pressure difference monitored by the pressure sensor 701, or by a difference in the amount of work the air compressor needs to do to keep the electrode inflated. then the pulse generator generates a signal in response to either of these two detected parameters and transmits this along the conductive lead 604 to electrically stimulate the muscles. This results in further contraction. aiding the patient in their squeezing action. Additionally, the pulse generator may be activated in response to an output from the electromyographic or perineometer sensor 703.

Any one or more of the above described internal electrodes can be used to perform Pelvic Floor Exercises. The preferred method is by using the

embodiment of Figure 33 in conjunction with Bio feedback and Facilitated Electrical Stimulation. In such exercise, a (female) patient, practices squeezing exercises by squeezing and relaxing against the resilience of the electrode.

The patient exercises by working muscles against the resilience of the core material, rather than by attempting to keep the core in situ.

Variations in the resilience and deformability of the core material 100 may be made to suit various exercises. A series of electrodes may be provided, each electrode being of a progressively increased deformability and/or resilience to provide a means of performing a programme of progressively more advanced exercises.

In the above described embodiments of insertable electrodes, the outer conductive sheath may be completely conductive over the whole of its surface, or may comprise one, two or more conductive bands incorporated therein. In either case, the conductive material contacts the wall of the tract to deliver an electrical signal thereto. The sheath may be constructed from flexible woven or knitted cloth or may be of stitched construction using conductive fibres. The sheath may be sewn or bonded to the core.

In each embodiment of the internal electrode, the connecting pigtail wires are preferably sewn or crimped to the sheath to be used for pulling the electrode during removal from the cavity.

A main advantageous feature of the various of the above embodiments may be an ability to multiplex facets an individual patient's treatment programme. For example, in Stress incontinence, the patient may follow a particular set of preset instructions for NTS treatment which would be intended to restore a pudendal nerve function and regenerate type I slow muscle fibres.

The treatment can be applied via a cutaneous perineal electrode and an arbitory indifferent electrode positioned on the buttock, thigh or abdomen, with the treatment pulse preset to a specified set of parameters by the smart card selected for this aspect of treatment.

In later weeks the treatment may require that the type I slow fibres require additional strengthening and the electrode system could then be changed for NMS treatment, by passing the pulse between the single banded tampon electrode and either a cutaneous perineal or arbitory indifferent electrode. The electrical parameters for the electrode drive signals could be provided in accordance with appropriate instructions contained in a second smart card.

At the end of the treatment, it may then be preferable to add to the strength of the type II fast fibres which may best be achieved by FES treatment, applied using a single double banded tampon electrode driven by a new selected drive signal in accordance with new instructions contained in a third smart card.

The final part of the treatment may include use of the bio-feedback facility.

Thus, a flexible treatment apparatus and system may be provided, using a single piece of equipment. In contrast, using prior art systems, a patient would possibly only receive one of the aforementioned modes of treatment, or alternatively, three separate sets of equipment would be necessary.

Specific embodiments of the invention may have an advantage of providing variable combinations of pulse geometry, intensity ceilings and preset treatment parameters to suit, in addition to urinary or faecal incontinence treatment, therapeutic requirements including Transcutaneous Electrical Nerve Stimulation (TENS), Functional Electrical Stimulation (FES), Neuro Muscular Stimulation (NMS), Neuro Trophic Stimulation (NTS), Interferential Therapy, Iontophoresis or Galvanism.

Specific embodiments of the invention may provide a versatile apparatus which provides a combination of electro-stimulation treatments available in a single unit. The module may have an advantage of being easily set by a clinician to provide a prescribed electro-stimulation treatment, yet be tamper proof by a patient.

Various of the embodiments may have an advantage of being capable of recording details of the administration of a prescribed treatment such that

a clinician can periodically monitor such administration when the patient is out of clinic.

The embodiments may advantageously provide an electro-stimulation apparatus which is portable by a patient, and can be preset to provide a drive signal having fixed parameters selected from a range of selectable drive signal parameters.

Specific embodiments of the present invention may have an advantage of providing means of treatment for incontinence using a flexible sheet material electrode.

The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents are incorporated herein by reference.

All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

Each feature disclosed in this specification (including any accompanying claims, abstract and drawings), may be replaced by alternative features serving the same, equivalent or similar purpose, unless expressly stated otherwise. Thus, unless expressly stated otherwise, each feature disclosed is one example only of a generic series of equivalent or similar features.

The invention is not restricted to the details of the foregoing embodiment(s). The invention extends to any novel one, or any novel combination, of the features disclosed in this specification (including any accompanying claims, abstract and drawings), or to any novel one, or any novel combination, of the steps of any method or process so disclosed.

CLAIMS

1. A portable electrical stimulation apparatus for treatment of incontinence, comprising:

one or more electrodes for applying one or more electrical stimulation signals to a patients body:

a signal generator for generating the electrical stimulation signal(s);

one or more conductive leads for connecting the signal generator to the electrode(s), to deliver the electrical stimulation signal to the electrode(s); and

a power supply.

characterised in that the apparatus includes an instruction storage means or a programming means for imparting a set of instructions to the signal generating means, the signal generating means being responsive to the instruction storage means or programming means so that the generated signal adopts signal waveform characteristics selected in accordance with said set of instructions.

2. An electrical stimulation apparatus as claimed in claim 1, characterised in that at least one electrode is applied in the vaginal or anal region, and at least one electrode is a surface electrode to be applied to a surface of the patients skin.

3. An electrical stimulation apparatus as claimed in claim 1, or 2, characterised in that the wave form characteristics of the electrical stimulation signal are not alterable by the patient, the waveform being determined from the normal neuronal activity of the patient, and applied so as to superimpose normal neuronal activity.

4. An electrical stimulation apparatus according to any one of claims 1 to 3, characterised in that said instructions comprise instructions on the selection of one or more of the following signal waveform characteristics:

pulse geometry type;
pulse width magnitude;
pulse train frequency;
pulse envelope type;
pulse envelope duration;
pulse envelope duty cycle;
treatment time;
signal intensity.

5. An electrical stimulation apparatus according to claim 4, characterised in that the pulse envelope duration is in the range 1 to 100,000 microseconds.

6. An electrical stimulation apparatus according to claim 4 or 5, characterised in that the pulse train frequency is in the range 200Hz to 5MHz.

7. An electrical stimulation apparatus according to claim 4, 5 or 6 characterised in that the envelope duty cycle is in the range 1 to 99%.

8. An electrical stimulation apparatus according to any one of claims 4 to 7, characterised in that the number of pulses per each envelope is in the range 1 to 20,000.

9. An electrical stimulation apparatus according to any one of claims 4 to 8, characterised in that the pulse envelope is of a sinusoidal, square wave or saw tooth type.

10. An electrical stimulation apparatus according to any one of claims 4 to 9, characterised in that the frequency with which the envelope occurs is in the range 0.1 to 2,000Hz.

11. An electrical stimulation apparatus according to any one of claims 4 to 10, characterised in that the pulse envelope occurs at a time in the duty cycle, which is random between successively generated envelopes.

12. An electrical stimulation apparatus according to any one of claims 1 to 11, characterised in that the instruction storage means is a smart card.

13. An electrical stimulation apparatus according to any one of claims 1 to 12, characterised in that the programming means is a personal computer.

14. An electrical stimulation apparatus according to any one of claims 1 to 13, characterised by having a data logging means for recording generation of the electrical stimulation signal, so as to provide a record of how often the electrical stimulation signal has been generated.

15. An electrode characterised by being adapted to attach to the surface of a perineal region, said electrode comprising a flexible conductive substantially sheet material.

16. An electrode according to claim 15, characterised by being adapted for use in the treatment of incontinence in that the size and flexibility of the electrode are selected so as to suit the anatomical contours of the vaginal or anal regions.

17. An electrode according to claim 15 or 16, characterised in that a length of said electrode is in the range 20 to 100 millimetres.

18. An electrode according to claim 17, characterised in that said length is in the range 40 to 60 millimetres.

19. An electrode according to any one of claims 15 to 18, characterised in that a width of said electrode is in the range 10 to 60 millimetres.

20. An electrode according to claim 19, characterised in that said width is in the range 20 to 40 millimetres.

21. An electrode according to any one of claims 15 to 20, characterised by having one or more concave perimeter portions.

22. An electrode according to any one of claims 15 to 21, characterised by one or more convex perimeter portions.

23. An electrode according to any one of claims 15 to 22, characterised in that said sheet material comprises any flexible conductive material.

24. An electrode according to any one of claims 15 to 23, characterised by an elongate centre portion of a first width and one or more protruding end portions of a second width, wherein said second width is greater than said first width.

25. An electrode characterised by being adapted to attach to the surface of the sacral region, so as to stimulate the nerves in the sacral region.

26. An electrode according to claim 25, having an aperture for the placement of a finger to correctly align the electrode in place in the sacral region.

27. An electrode characterised by being adapted to be insertable into an anatomical cavity or tract, said electrode comprising a plug having a core of a substantially expandable and/or compressible material.

28. An electrode according to claim 27, characterised in that said material is deformable or resilient.

29. An electrode according to claim 28, characterised in that the core material of said plug has a Shore hardness of below 45, and preferably below 30.

30. An electrode according to claim 27, 28 or 29, characterised in that said foam material is a polyvinyl formal foam (PVF) material.

31. An electrode according to claim 27, 28 or 29, characterised in that said core material is a paper or cotton material.

32. An electrode according to any one of claims 27 to 31, characterised in by having a conductive sheath surrounding at least partially said core.

33. An electrode according to claim 32, characterised in that said conductive sheath is of a woven or knitted fibre, for example stainless steel, gold or other electro-plated precious metal.

34. An electrode according to any one of claims 27 to 33, characterised by having a conductive lead adapted for carrying a drive signal to said conductive material and for removing said electrode from said cavity.

35. An electrode according to any one of claims 27 to 34, characterised in that the core has a hollow passage for the insertion of a rigid member for supporting the core during insertion into the cavity or tract.

36. An electrode according to any one of claims 27 to 35, characterised by having a first said conductive sheath and a second said conductive sheath, said sheaths being electrically isolated from each other, said sheaths having respective first and second electrical connection means thereto.

37. An electrode according to claim 36. characterised by being adapted for use in F.E.S. treatment of incontinence.

38. An electrode according to any one of claims 27 to 37, characterised by having a length in the range 30 to 100 millimetres, suitably in the range 45 to 65 millimetres.

39. An electrode according to any one of claims 27 to 38, characterised by having a width or diameter in the range 10 to 40 millimetres.

40. An electrode according to any one of claims 27 to 39, characterised by further comprising a conductive sheath surrounding at least partially said plug.

41. An electrode according to claim 40, characterised in that said conductive sheath is of a woven or knitted cloth.

42. An electrode according to any one of claims 27 to 41 characterised by being adapted for insertion of a rigid support member to support the electrode during insertion of said electrode into said cavity or tract, said support member being removable once said electrode is deployed therein within said cavity or tract.

43. An electrode according to any one of claims 27 to 42, adapted for deployment in said cavity or tract by insertion of a hollow tubular applicator containing said electrode in compression, in to said cavity or tract, followed by subsequent removal of said applicator from the cavity or tract, allowing expansion of said electrode within said cavity or tract.

44. A tampon electrode for insertion into the vagina or anus of a patient, the electrode comprising:

an outer sheath having a conductive outer surface for imparting an electrical stimulation signal to the vaginal or anal wall; and

a conductive lead for supply of the electrical stimulation signal to the electrode;

characterised in that the outer sheath is expandable and contractible such that the sheath can be inflated or deflated whilst in position in the vagina or anus.

45. An electrode according to claim 44, characterised by having a rigid inner member around which the outer sheath is arranged, such that when the electrode is in the deflated condition, the rigid inner member lends the electrode sufficient rigidity so as to enable the electrode to be pushed into the vagina or anus for insertion therein.

46. An electrode according to claim 44 or 45, characterised in that the electrode has a fluid supply tube connected thereto for delivery of a pressurised fluid to the electrode for inflation thereof.

47. An electrode according to any one of claims 44 to 46, characterised in that the electrode is inflatable by an increase in air pressure within the outer sheath.

48. An electrode according to any one of claims 44 to 47, characterised in that the outer sheath is of an elastic material.

49. An electrode according to claim 48, characterised in that said elastic material is a silicon rubber.

50. An electrode according to any one of claims 44 to 49, characterised in that the conductive outer surface comprises a woven or knitted conductive cloth attached to the outer sheath.

51. A sensing apparatus for sensing the condition of muscles in the vaginal or anus region, characterised by comprising:

a tampon electrode for insertion into the vagina or anus, the tampon electrode capable of transmitting a pressure signal in response to an increase in pressure exerted on the electrode by the vaginal or anal muscles;

a pressure sensor means for sensing the signals, the pressure sensing means producing an output dependent on the pressure exerted on the electrode by the vaginal or anal muscles.

52. A sensing apparatus according to claim 51, characterised in that the pressure signal is a pneumatic signal or an hydraulic signal, generated in response to pressure exerted on an expandable or contractible electrode.

53. A sensing apparatus according to claim 51 or 52, characterised in that the electrode is inflatable and there are provided means for inflating the electrode.

54. A sensing apparatus according to any one of claims 51, 52 or 53 characterised in that the electrode has a conductive outer surface for applying an electrical stimulation signal to the vaginal or anal region, and the sensing apparatus includes a signal generator for generating the electro-stimulation signal, and includes a conductive lead for delivery of the electrical stimulation signal from the signal generator to the electrode.

55. A sensing apparatus according to claim 54, characterised by having an electro-myographic or perineometer sensor, which receives an electrical signal from the conductive outer surface of the electrode via the conductive lead, the signal generator being arranged to produce an electro-stimulation signal in response to an output from the electro-myographic or perineometer sensor.

56. A sensing apparatus according to any one of claims 51 to 55, characterised by having a sacral, anal, perineal, or vaginal electrode, or an electrode placed on the buttock.

57. A sensing apparatus according to any of claims 51 to 56, characterised in that the sacral or buttock electrode serves as a reference or ground electrode.

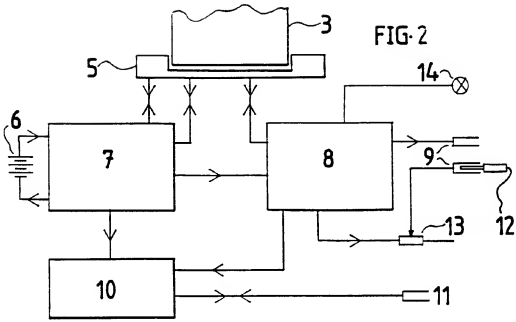
58. A sensing apparatus according to any one of claims 51 to 57, characterised by being adapted for use as a means of facilitation of muscles in the vaginal region or anal region.

59. A sensing apparatus as claimed in any one of claims 51 to 58, characterised by having a display or a data recording means.

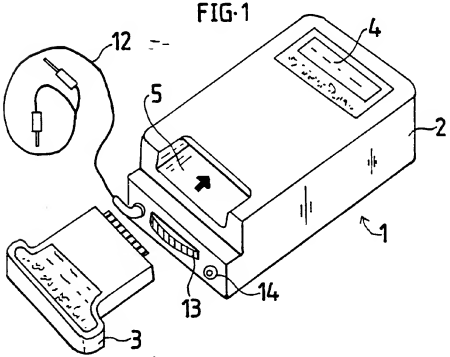
60. An indifferent electrode for attachment to the buttock of a patient, the indifferent electrode having an area of approximately twice that of the sacral or perineal electrode

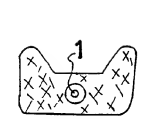
61. An indifferent electrode as claimed in claim 60, characterised by being shaped and sized so as to fit over the sacral spine, spinuous processes S2, S3, or S4.

FIG·2



FIG·1





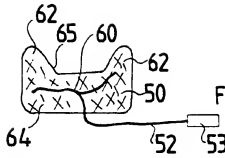
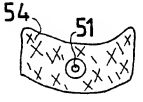


FIG. 3



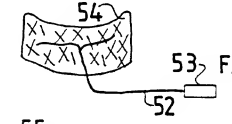
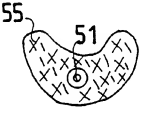


FIG. 4



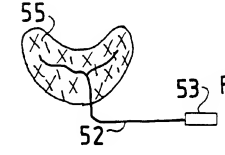


FIG. 5

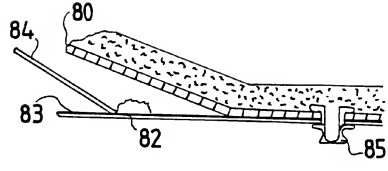


FIG. 8

FIG. 6

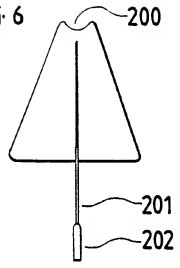


FIG. 7

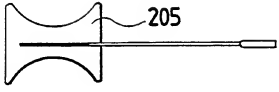


FIG. 9

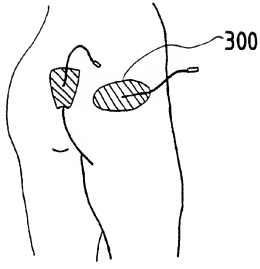


FIG. 10

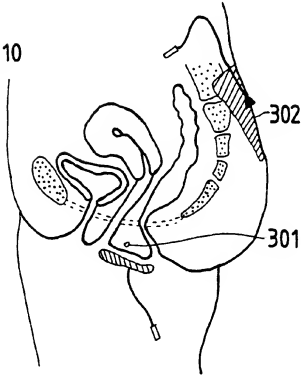


FIG. 11

FIG. 12

FIG. 13

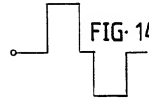


FIG. 14

FIG. 15

FIG. 16

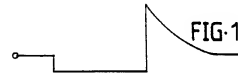


FIG. 17

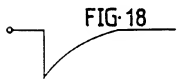


FIG. 18

FIG. 19

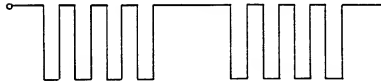


FIG. 20

FIG. 21

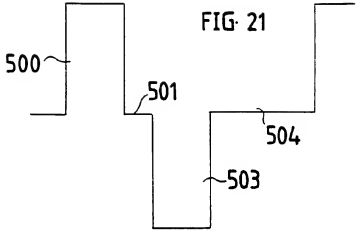


FIG. 22

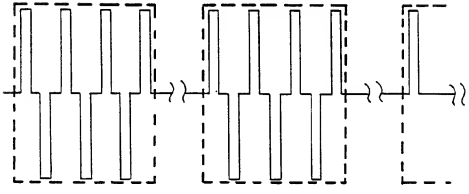
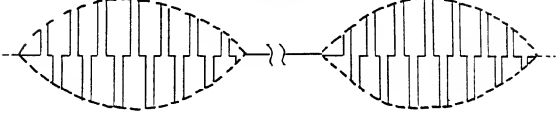


FIG. 23



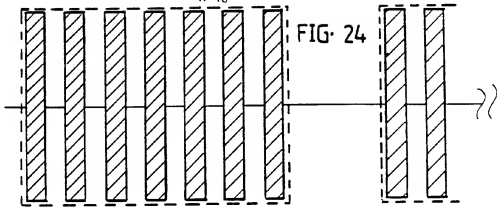


FIG. 24

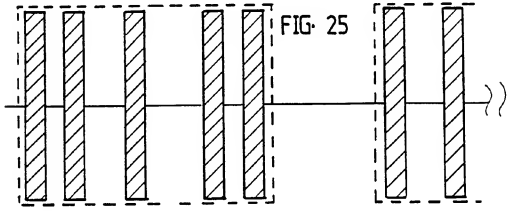


FIG. 25

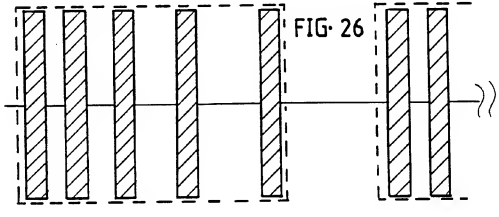


FIG. 26

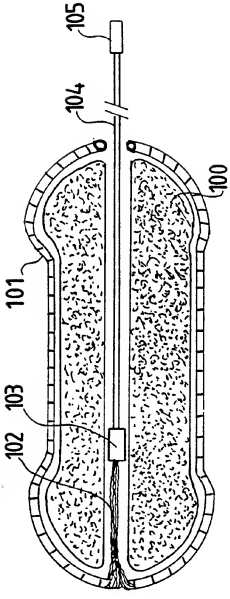
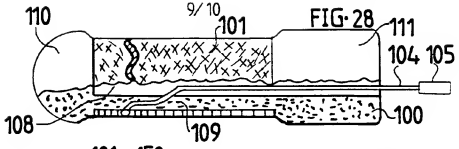
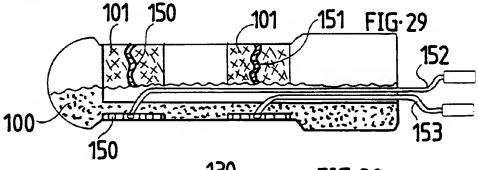


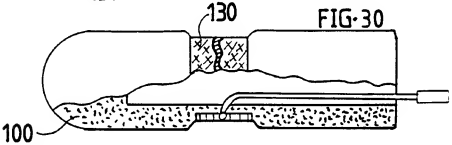
FIG. 27



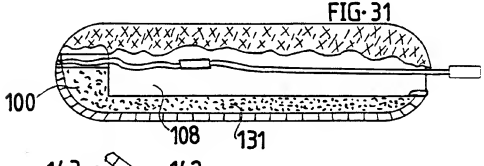
FIG·28



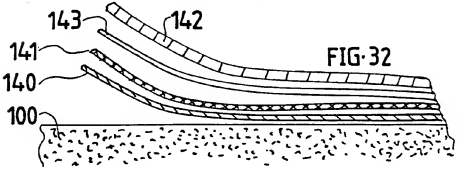
FIG·29



FIG·30



FIG·31



FIG·32

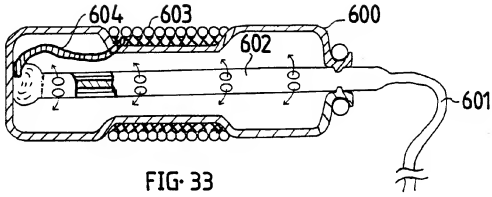


FIG. 33

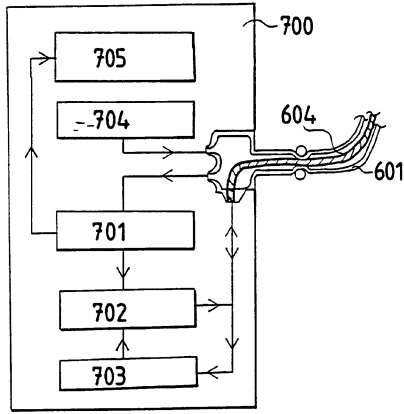


FIG. 34

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 93/01059

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61N1/05 A61N1/36 A61B5/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP,A,0 116 688 (S.R.STEINDORF) 29 August 1984	1-14,57
A	see the whole document	27-43, 60,61
Y	EP,A,0 197 889 (BBC-SECHERON S.A.) 15 October 1986 see the whole document	1-14
X	EP,A,0 201 271 (BIOMEDICAL RESEARCH LTD.) 12 November 1986 see the whole document	1
X	US,A,5 046 511 (D.D.MAURER ET AL.) 10 September 1991	15,16
Y	see the whole document	17-24

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 October 1993	13. 10. 93

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+ 31-70) 340-3016	HUNT, B

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	see the whole document cited in the application	60,61
X	EP,A,0 245 547 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 19 November 1987 see the whole document	25
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Y	see the whole document	51-56,58
Y	US,A,3 640 284 (P.A.DE LANGIS) 8 February 1972 see the whole document	51-56,58
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